

## SUBSTITUTE SPECIFICATION

## TITLE OF THE INVENTION

METHOD FOR ANALYZING EFFECTIVENESS OF PHARMACEUTICAL PREPARATION

## CROSS REFERENCE TO RELATED APPLICATIONS

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[0001] This application is based on and hereby claims priority to German Application No. 102 366 30.6 filed on August 9, 2002, the contents of which are hereby incorporated by reference.

## BACKGROUND OF THE INVENTION

## 1. Field of the Invention

[0002] The invention relates to an analysis of the effectiveness of a pharmaceutical preparation or medical preparation.

## 2. Description of the Related Art

[0003] An analysis of the effectiveness of a new medical preparation or new medicine as part of an approval procedure is known from Arzneimittelforschung und -entwicklung (Pharmaceutical research and development), available on August 06, 2002 at the medicine worldwide website in Germany ([www.m-ww.de](http://www.m-ww.de)) on the pages devoted to "Pharmakologie Pharmaforschung".

[0004] During an approval procedure of this kind the new medicine requiring approval passes through different (test) phases, phase 1 to phase 3, within which the effectiveness of the new medicine requiring approval in combating a specific disease has to be demonstrated. A further object of an approval procedure of this kind is to examine side-effects of the new medicine requiring approval as well as to test the effectiveness of the new medicine requiring approval in comparison with other similarly effective medicines.

[0005] The effectiveness tests are mostly conducted on the basis of studies carried out on test participants to whom the new medicine requiring approval is administered. The effectiveness of the new medicine is assessed on the basis of results from interviews, psychological tests and behavioral studies that are conducted with the test participants.